

09/080,140



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/080,140 05/15/98 BILLING-MEDEL

P 6105.US.P1

EXAMINER

HM22/0314

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JOHNSON, N PAPER NUMBER

12

1642
DATE MAILED:

03/14/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on election of 11/23/99
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 10-16, 25, 30, 33, 35, 38-39 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 10-16, 25, 30, 33, 35, 38-39 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT: Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). filed 12/28/98 and 8/13/98
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

1. Applicant's election of Group II, claims 10-16, 25, 30, 33, 35, 38-39 in Paper No. 11, mailed 5/27/99 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-9, 17-24, 26-29, 31-32, 34, 36-37, 40-44 have been canceled.
Claims 10-16, 25, 30, 33, 35, 38-39 are examined on the merits.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should reflect that the claimed invention is drawn to polynucleotide sequences.

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

"NONE" is listed with statement I hereby claim benefit under USC 120 or the following earlier filed U.S. patent application.

It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

5. References lined through on the IDS filed 6/19/98 have not been considered by the examiner, as parent application 08/856,653 was unavailable to the examiner. Applicant is invited to provide replacement copies.

6. Claims 10-16, 25, 30, 33, 35 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite in the recitation "useful for detecting PS116 polynucleotides in a test sample." It is unclear how the intended use of the claimed test kit modifies the various components comprising the claimed test kit.

The following recitations are vague and indefinite; "PS116 polynucleotide" (claims 10, 33), "PS116 gene" (claim 11), "PS116 epitope (claims 14, 25, 30), "open reading frame derived from PS116" (claim 15) and "PS116 protein" (claim 38). "PS116" is a laboratory designation whose identity is not art known. Absent limitations directed at identifying structural or functional characteristic (such as a SEQ ID NO:), the metes and bounds of what qualifies as a PS116 polynucleotide or polypeptide is unclear.

Claim 11 is vague and indefinite in the recitation "derived from" a PS116 gene." The nature of the derivation processes encompassed by the claim are unclear.

Absent the recitation of specific hybridization conditions, the metes and bounds of the polynucleotides claimed in claim 11 are unclear.

The recitation "selectively hybridizing to" in claim 11 is vague and indefinite. The exact type of hybridization encompassed by this term is unclear.

7. Claims 10-16, 25, 30, 33 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 is drawn to test kits comprising at least one polynucleotide "having at least 50% identity with a sequence selected from the group consisting of SEQ ID NO:1-12, and fragments or complements thereof."

Claim 11 is drawn to a "purified polynucleotide or fragment thereof" "wherein said polynucleotide" "has at least 50% identity with a sequence selected from the group consisting of

SEQ ID NO:1-12, and fragments or complements thereof.” Claim 14 is drawn to these polynucleotides, “wherein said polynucleotide comprises a sequence encoding at least one PS116 epitope.”

Claim 15 is drawn to recombinant expression systems “comprising a nucleic acid sequence,” “wherein said nucleic acid sequence has at least 50% identity with a sequence selected from the group consisting of SEQ ID NO:1-12, and fragments or complements thereof.”

Claim 25 is drawn to polynucleotides encoding polypeptides, “wherein said polypeptide comprises an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27, SEQ ID NO:28, SEQ ID NO:29, and fragments or complements thereof.”

Claim 30 is drawn to cells transfected with a nucleic acid sequence encoding at least one ... epitope, wherein said nucleic acid sequence is selected from the group consisting of SEQ ID NO:1-12 and fragments or complements thereof.”

Claim 33 is drawn to a composition of matter comprising a “polynucleotide or fragment thereof, wherein has at least 50% identity with a polynucleotide selected from the group consisting of SEQ ID NO:1-12 and fragments or complements thereof.”

For examination purposes, the recitation of the following Markush group format in the claims; “a sequence selected from the group consisting of SEQ ID NO:1-12, and fragments or complements thereof,” is interpreted to be the Markush group of each of the SEQ ID NO:1-12, all the various fragments of each of SEQ ID NO:1-12 and the complements of each of SEQ ID NO:1-12.

Thus, all of the above claims are drawn to nucleic acid molecules that are only at least 50% identical to the exemplified sequences of SEQ ID NO:1-12 or minimally contain only portions of the novel nucleic acid molecules identified in the specification. Thus, the claims read on a genus of molecules, including any full length gene which contains these small portions of sequence, any fusion construct or other cDNAs and polynucleotide sequences that are minimally identical (at least 50% identical) to SEQ ID NO:1-12. In the cases of small identified nucleic acid sequences claimed with open language (comprising, has, having) or with minimal % identity to a

reference sequence, the genus of a nucleic acid molecules encompasses a variety of subgenera with widely varying attributes. The specification discloses only the structural features of nucleic acid molecules consisting of each of the disclosed SEQ ID NO (SEQ ID NO:1-12) and nucleic acid molecules **consisting** of defined fragments thereof.

Thus, one of skill in the art would not understand that the applicant had possession of the large collection of polynucleotides encompassed by the claims at the time the instant application was filed. Applicant is referred to the interim guidelines concerning compliance with the written description requirement of 35 USC 112, first paragraph published in the Official Gazette and also available at www.uspto.gov.

8. Claims 10-16, 25, 30, 33, 35, 38-39 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility. As discussed in the above paragraph, claims 10-16, 25, 30, 33 and 35 are drawn to nucleic acid molecules that minimally contain only portions of the novel nucleic acid molecules identified in the specification. Additionally, claim 38 is drawn to a gene, or fragment thereof, which codes for a ... protein having an amino acid sequence with at least 50% identity to SEQ ID NO:25" and claim 38 is drawn to a gene or fragment thereof, comprising DNA having at least 50% identity with SEQ ID NO:11 or SEQ ID NO:12. The specification asserts no specific or substantial utility for this wide collection of polynucleotides.

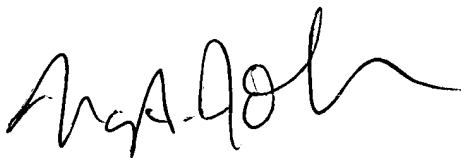
Claims 10-16, 25, 30, 33, 35, 38-39 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9. Claims 11-16 and 38-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 11-14 are drawn to polynucleotides "derived from a PS116 gene," claims 15-16 are drawn to "a nucleic acid sequence that includes an open reading frame derived from PS116," claim 38 is drawn to "a gene ... which codes for a PS116 protein," and claim 39 is drawn to "a gene ... comprising DNA having at least 50% identity with SEQ ID NO:11 or SEQ ID NO:12." Thus, all claims are broadly drawn to a PS116 gene. The specification describes only the various overlapping cDNA sequences SEQ ID NO:1-12. The specification does not describe any of the structural elements of a gene that would encode these various cDNA sequences. For example, the specification does not describe the organization, location or actual DNA sequence of promotor and regulatory regions and introns, all functional elements of a "gene." Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the interim guidelines concerning compliance with the written description requirement of 35 USC 112, first paragraph published in the Official Gazette, also available at www.uspto.gov.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



NANCY A. JOHNSON, PH.D
PRIMARY EXAMINER

March 12, 2000